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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

BANSAL, G

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/02/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/529659

Applicant(s)

Wagner et al

Examiner

Epelita Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on 8/10/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 15 - 28 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 15 - 28 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1642

### DETAILED ACTION

1. Applicant's amendment filed 8/10/2000 (Paper No:6/A) is acknowledged. Accordingly, claims 1-14 have been canceled without prejudice, and claims 15-28 have been added.

Claims 15-28 are being examined.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porgador et al (1993) in view of Saravolac et al (1996) or Cleland et al (1996) or Fujioka et al (1995) - all these are cited on the PTOL-1449.

Claims are drawn to tumor vaccines which contain in addition to a tumour antigen source a release system for the delayed release of IFN- $\gamma$ , the effective dose being 50ng to 5 $\mu$ g, the release period being ½ hour to 8 days. Porgador et al teaches that tumor vaccines based on irradiated genetically altered tumor cells which secrete IFN- $\gamma$  in high or low concentrations (see Abstract for e.g.). The use of IFN- $\gamma$  secreting tumor cells provides a source of IFN- $\gamma$  along with the tumor antigens in order to induce or elicit an immune response against the tumor. The presence

Art Unit: 1642

of IFN- $\gamma$  as an important mediator of this vaccine efficacy is taught by Porgador et al (Reference AS on page 13 of PTO1449; see pg. 1467, first paragraph as well as in the rest of the Discussion section). IFN $\gamma$  is secreted in a maximal concentration of 256 I.U./ml which could correspond to a concentration of approximately 100 ng/ml (Table 1, page 1462 and as evidenced by Hermann et al, 1995; Reference AR on page 6 in PTO1449. Herman et al teaches that 50,000 IU IFN- $\gamma$  corresponds to a concentration of approximately 25 ug/ml). The claims are not drawn to any release systems into which IFN- $\gamma$  has been incorporated and from which it is slowly released. Saravolac et al (1996; reference AS on page 12) or Cleland et al (1996; reference AS on page 3) or Fujioka et al (1995; reference AR on page 16) all teach slow release systems that are either liposomes, or microspheres or minipellets that have been used for the delivery of IFN- $\gamma$ . Saravolac also teaches that the amount of IFN- $\gamma$  released by the liposomes is within the range of amounts as claimed, by adjusting the amount of liposomes administered to the subject (see page 202, section 2.7). It appears that the IFN- $\gamma$  was present as late as 10 days. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to combine the teachings of Porgador et al and Saravolac et al or Cleland et al or Fujioka et al to produce a vaccine composition comprising the tumor antigens and slow release systems delivering IFN- $\gamma$ . One of ordinary skill in the art would have been motivated to do so because it would be definitely advantageous to have a source of IFN- $\gamma$  in a slow release system that would be available readily to mix with tumor antigen where there is a need to change the tumor antigen. By having a ready source of the cytokine release system, one of ordinary skill in the art would know that the only variable would be the source of antigen to be added to the composition, and therefore the process of preparing these vaccines is simplified. The teachings of both Porgador et al and Saravolac et al or Cleland et al or Fujioka et al provide a reasonable expectation of success that such vaccine compositions can be made and are within the purview of one of ordinary skill in the art to manipulate the amounts of the ingredients to produce the claimed compositions.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1642

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 15 is ambiguous in the recitation of "active substance for IFN- $\gamma$ ".

B. It is not clear in claim 15 if the effective dose is 50ng or 5ug over an 8 day period or 50ng or 5ug over a 1/2 hour period. Clarity of the effective dosage and the release kinetics is requested to make definite what is effective.

C. Claim 26 is ambiguous in the recitation of "tumor cells charged with peptides".

7. No claim is allowed.


8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 3995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 25, 2001

  
GEETHA P. BANSAL  
PRIMARY EXAMINER